

R E M A R K S

Claims 1-3, 7, and 9 are pending and under examination. The claims have been rejected under 35 U.S.C. 103 as obvious over Cook et al. (US Pat. No. 5,554,646) in view of Kawamura et al. (Hypertension 27:408-413 (1996)). The Examiner states that Cook et al. discloses a method of reducing body fat by administering CLA. The Examiner admits that Cook et al. does not teach the use of CLA to treat hypertension. The Examiner states that Kawamura et al. teach that reduction in body weight in overweight human patients correlates to a reduction in hypertension and that this provides a “nexus teaching between hypertension, weight loss and decreases in blood pressure.” Office Action at p. 3.

Applicant's respectfully submit that the Examiner has not established a *prima facie* case of obviousness. A *prima facie* case of obviousness requires the Examiner to cite a combination of references which (a) disclose the elements of the claimed invention, (b) suggests or motivates one of skill in the art to combine those elements to yield the claimed combination, and (c) provides a reasonable expectation of success should the claimed combination be carried out. Failure to establish any one of the these three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles Applicant to allowance of the claims at issue.¹ The claims are not obvious because the cited references do not provide a motivation to combine and do not provide a reasonable expectation of success.

In responding to Applicant's previous arguments, the Examiner states:

First, Kawamura et al. provide a nexus teaching between weight loss in hypertensive patients and lowering of blood pressure. It remains obvious to one of ordinary skill in the art that the method of Cook et al. can lower blood pressure via weight loss. The Examiner did not assert that CLA would have a positive or negative on hypertension like ephedrine as submitted by Applicant. The Examiner asserts that weight loss is directly related to lowering of blood pressure, as supported by Kawamura et al., and CLA can be used to effect weight loss as taught by Cook et al. Secondly, one of ordinary skill in the art would have a reasonable expectation of success because of the nexus teaching of Kawamura et al.

However, these arguments are scientifically incorrect. The Examiner's attention is directed to the accompanying declaration by Asgeir Saebo. As Mr. Saebo indicates, “When a

¹ See, e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

biologically active agent, such as CLA, is administered to a subject there can be a variety of effects. Just because CLA causes weight loss does not also mean that it would reduce hypertension. A person of skill in the art would not reasonable expect CLA to reduce hypertension for two reasons.” The first reason is that CLA has been shown to elevate F2-isoprostance, a known vasoconstrictor. Second, other agents used for weight loss actually cause hypertension. As further indicated by Mr. Saebo, how an agent such as CLA acts in the body is complex. Whether CLA causes an increase or decrease in hypertension, or has no effect at all, is determined by a variety of factors that have no relation to weight loss. It is not scientifically valid to draw a conclusion that because an agent causes weight loss, it can also be expected to decrease hypertension. The references cited by the Examiner contain no data that can be interpreted in this manner.

Accordingly, Applicants respectfully submit that the Examienr has failed to establish a prima facie case of obviousness because there is no motivation to combine and no reasonable expectation of success. Specifically, the Federal Circuit held that:

The factual inquiry whether to combine references must be thorough and searching. It must be based on **objective evidence** of record. **This precedent has been reinforced in myriad decisions, and cannot be dispensed with.**²

Applicants respectfully submit that the Examiner’s motivation to combine does not meet this standard. As indicated by Dr. Saebo, a person of kill in the art would not interpret the data in the cited references as the Examiner has and could not reach the same conclusions regarding motivation to combine.

Furthermore, as indicated by Mr. Saebo, just because a biologically active substance causes weight loss does not mean that the substance will or will not treat hypertension or cause hypertension. Empirical experimentation is required to determine if the biologically active substance will be antihypertensive or prohypertensive. Again, one need look no further than the fact that ephedrine, a substance known to useful for causing weight loss, causes hypertension. There is no way to predict whether a given agent will cause hypertension, prevent hypertension, or be nonactive with respect to hypertension without testing the substance. Not all agents that

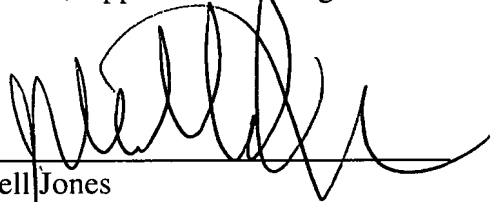
² See, *In re Lee*, 277 F.3d 1338, 1344 (Fed. Cir. 2002); internal citations omitted; emphasis added.

cause weight loss cause a reduction in hypertension. Thus, there was no likelihood of success in using CLA to treat hypertension.

CONCLUSION

It is respectfully submitted that the invention as claimed fully meets all requirements for patentability and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

Dated: April 25, 2007



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